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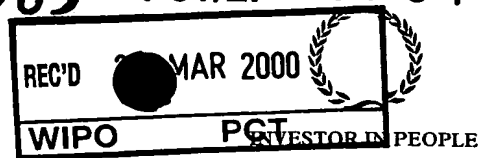
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2. Patent application number **5 AUG 1999 9918388.1**  
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3. Full name, address and postcode of the or of each applicant (underline all surnames)  
**GLAXO GROUP LIMITED  
GLAXO WELLCOME HOUSE  
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UNITED KINGDOM**

Patents ADP number (if you know it)

473587003

If the applicant is a corporate body, give the country/state of its corporation

4 Title of the invention **METERING VALVE**

5 Name of your agent (if you know one) **DR CHRISTOPHER GERARD PIKE  
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SL7 2BT**  
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Country	Priority application number (if you know it)	Date of Filing (day / month / year)
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11. I request the grant of a patent on the basis of this application

Signature Christopher Gerard Pike  
**AGENT FOR THE APPLICANTS**

4 August 1999

12. Name and daytime telephone number of person to contact in the United Kingdom

Dr. Christopher G. Pike  
01628 471869

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### Metering valve

This invention relates to a metering valve for an aerosol container. The valve is particularly suitable for use in the metered dispensing of medicament by way of an inhalation device.

It is known to dispense medicament in aerosol form from a metered dose inhalation device. Such devices commonly comprise a housing and supported therein, a container for the aerosol formulation. The container has a metering valve which generally is a slide or rotary valve. The slide or rotary valve comprises a valve stem which is movable against a restraining, generally frictional, force within a valve body from a dispensing position to a non-dispensing position.

In more detail, a slide valve typically comprises a valve body and within the valve body a sealing ring. A valve stem having a dispensing passage therein is frictionally received by the sealing ring. The valve stem is slidably movable within the sealing ring from a valve-closed position to a valve-open position in which the interior of the valve body is in communication with the dispensing passage. An illustrative slide valve is described in PCT application no. WO96/28367.

Actuation of a slide valve involves the application of sufficient mechanical force to overcome the frictional force between the valve stem and the sealing ring.

In currently marketed inhalation devices the mechanical force required to actuate the slide valve is generally of the order of 20-40N. This force is often supplied by the patient manually depressing the container and valve body attached thereto relative to the housing and valve stem supported thereby. The movement of the valve body relative to the valve stem results in actuation of the valve and hence release of medicament.

With some current inhalation devices having a slide or rotary valve the valve stem tends to stick, pause, or drag during the actuation cycle with the result that the patient perceives a 'notchiness' as the valve stem is moved. This may be partly caused by medicament sedimenting or precipitating out of the aerosol

formulation and depositing on the internal valve components, the presence of medicament on the sliding interface increasing the frictional force between the valve stem and the frictional seal. Various solutions to the problem of valve notchiness have been suggested including the use of lubricant on the valve stem and the seal.

It may be understood that effective delivery of medicament to the patient using an inhalation device as described above is to an extent dependent on the patient's ability to co-ordinate the actuation of the device (e.g. firing of the aerosol) with the taking of a sufficiently strong inward breath. The required co-ordination can present difficulties to some patients, with the risk that these patients do not receive the appropriate dose of medicament. There have thus, been efforts to develop inhalation devices which do not rely on manual actuation by the patient, in particular those which are actuatable in response to the breath of a patient. These devices are often known as breath-actuatable devices.

Breath-actuatable devices typically comprise a source of stored energy which on release actuates the slide valve of the medicament container and hence releases medicament, and a breath trigger which triggers the release of the stored energy in response to the breath of the patient. The stored energy source is required because the force required to actuate the slide valve (e.g. 20-40N as mentioned above) is too great to be suppleable by the patient's breath alone. Illustrative breath-actuatable devices are described in U.S. patent no. 5,655,523.

The applicants have now developed a metering valve which may be actuated without any need for a dispensing stem to be moved relative to a valve body. Since the new valve requires no relative movement of a valve stem to the valve body the problem of 'notchiness' associated with current slide valves is eliminated.

The newly developed metering valve is furthermore, operable by the application of a significantly lower force than is required to operate a conventional metering valve having a slide or rotary valve. The force required can indeed, be so low that the valve is actuatable by the force of a patient's breath alone. The present metering valve is thus, particularly suitable for use in breath-activated devices.



Such devices can be much simpler than current breath-actuated devices because they do not necessarily require a source of stored energy.

5 According to the present invention there is provided a metering valve for an aerosol container comprising a valve body defining a metering chamber; said metering chamber having an inlet and an outlet, said inlet permitting flow of aerosol from said container to the metering chamber and said outlet permitting dispensing of aerosol from the metering chamber; the inlet having an inlet valve reversibly actuatable from an open to a closed position; and the outlet having an  
10 outlet valve reversibly actuatable from a dispensing to a non-dispensing position, wherein said outlet valve comprises a outlet valve seat and an outlet valve poppet in biasable contact therewith.

15 As used herein the term valve poppet means any element which is receivable by a valve seat to form a valve seal and which is movable from the valve seat to break the valve seal. The valve poppet can be of essentially any suitable shape.

20 Preferably, the metering valve forms a single integral unit which may conveniently be fitted onto known aerosol containers for use in the dispensing of medicament.

25 Preferably, the inlet valve comprises an inlet valve seat and an inlet valve poppet in biasable contact therewith.

30 Preferably, the valve additionally comprises an outlet valve mover for moving the outlet valve poppet out of contact with the outlet valve seat.

35 Preferably, the valve additionally comprises an inlet valve mover for moving the inlet valve poppet out of contact with the inlet valve seat.

Preferably, either or both of said inlet valve mover or said outlet valve mover is mechanically actuatable. That is to say, actuatable by application of mechanical force either directly or through a mechanism capable of transferring mechanical force.

Preferably, either or both of the inlet valve mover or the outlet valve mover is electrically actuable. That is to say actuable by application of electrical current. More preferably, either or both of the inlet valve mover or the outlet valve mover comprises a multi-component strip or wire which is deformable in response to electrical current flow.

Suitable multi-component strips typically comprise a plurality of layers of material, each material having a different coefficient of thermal expansion. Preferred examples of multi-component strips include strips comprising multiple layers of different metals (e.g. bimetallic strips) and strips comprising at least one piezoelectric or piezoresistive material. Suitable piezoelectric materials include piezoelectric ceramics, such as compounds of lead zirconate and lead titanate, and piezoelectric crystals which are generally polycrystalline ferroelectric materials with the perovskite structure.

Suitable multi-component wires typically comprise alloys of two or more metals wherein one or more of the metals undergoes a temperature induced phase change in response to electrical current flow. Preferred examples of multi-component wires include those comprised of alloys of titanium and nickel which contract when electric current is applied.

Preferably, either or both of the inlet valve mover or the outlet valve mover is magnetically actuable.

Preferably, either or both of the inlet valve mover or the outlet valve mover comprises magnetic material or material which is magnetically inductive, that is to say material into which magnetism can be induced. The material may be permanently or non-permanently magnetisable.

Preferably, either or both of the inlet valve mover or the outlet valve mover is pneumatically actuable.

Preferably, either or both of the inlet valve mover or the outlet valve mover is hydraulically actuable. More preferably, either or both of the inlet valve mover or

the outlet valve mover comprises means, such as a fluid-filled bag or tube capable of transferring hydraulic force.

5 Preferably, the outlet valve poppet and/or the inlet valve poppet comprises an element in the form of a ball, a mushroom, a cone, a disc or a plug.

Preferably, the valve body additionally defines a sampling chamber and the inlet permits flow from the sampling chamber to the metering chamber.

10 Preferably, the metering chamber is of variable volume. The volume of the metering chamber may for example be varied to provide the optimum amount of medicament for release. In one preferred aspect, the volume of the metering chamber is variable automatically in response to a dosing signal sent from an electronic information processor.

15 Various types of variable volume metering chambers are envisaged. Suitable chambers comprise a fixed volume chamber whose metering volume is variable by insertion of a plunger or piston. The piston or plunger may have fixed form or alternatively may comprises an element of variable shape and volume such as  
20 an inflatable balloon. Other suitable chambers comprise a chamber which is expandable because it is formed from a flexible/expandable material. Further suitable chambers have telescopic or concertina arrangements to allow for mechanical expansion of the metering volume.

25 According to another aspect of the present invention there is provided an aerosol container comprising a metering valve as described above.

In a preferred aspect the valve body of the metering valve is not movable relative to the container. Also, the metering valve contains no movable stem. This  
30 contrasts with current slide valves where actuation of the valve is achievable by relative movement of the aerosol container to the valve stem.

In one aspect, the aerosol container comprises a suspension of a medicament in a propellant. More preferably, the propellant is liquefied HFA134a, HFA-227 or  
35 carbon dioxide. More preferably, the medicament is selected from the group

consisting of albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate, salts or solvates thereof and any mixtures thereof.

5 In another aspect, the aerosol container comprises a compressed gas, preferably compressed air.

10 According to a further aspect of the present invention there is provided an inhalation device for dispensing medicament to a patient comprising a housing; an aerosol container, locatable within said housing, said aerosol container comprising a metering valve as described above; and an outlet valve trigger for triggering the movement of the outlet valve poppet out of contact with the outlet valve seat.

15 When the aerosol container comprises an inlet poppet valve the inhalation device preferably also comprises an inlet valve trigger for triggering the movement of the inlet valve poppet out of contact with the inlet valve seat.

20 Preferably, either or both of said outlet valve trigger or said inlet valve trigger is triggerable in response to the breath of a patient.

25 Preferably, either or both of the outlet valve trigger or the inlet valve trigger communicates with a sensor which senses the breath of a patient.

30 In one aspect, the sensor comprises an breath-movable element which is movable in response to the breath of a patient. Preferably, the breath-movable element is selected from the group consisting of a vane, a sail, a piston and an impeller.

35 In another aspect, the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a patient.

In a further aspect, the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a patient.

In a further aspect, the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a patient.

5 In a further aspect, the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a patient.

In a further aspect, the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a patient.

10 In a further aspect, the sensor comprises a piezoelectric or piezoresistive element.

The outlet valve trigger and the inlet valve trigger may be independently triggerable or they may be triggerable in a coupled fashion.

15 Preferably, either or both of the outlet valve trigger or the inlet valve trigger is a mechanical trigger. In one aspect, the mechanical trigger comprises a lever mechanism. In another aspect, the mechanical trigger comprises a torque transfer mechanism.

20 Preferably, either or both of the outlet valve trigger or the inlet valve trigger comprises comprises a multi-component strip which is deformable in response to electrical current flow. The multi-component strip typically comprises a plurality of layers of material, each material having a different coefficient of thermal expansion. Preferred examples of multi-component strips include strips comprising multiple layers of different metals (e.g. bimetallic strips) and strips comprising at least one piezoelectric or piezoresistive material.

25 Preferably, either or both of the outlet valve trigger or the inlet valve trigger is a magnetic trigger.

30

In one aspect, the outlet valve trigger interacts magnetically with the outlet valve poppet and/or the inlet valve trigger interacts magnetically with the inlet valve poppet.

35

In another aspect, the outlet valve trigger interacts magnetically with a outlet shuttle contacting the outlet valve poppet and/ or the inlet valve trigger interacts magnetically with a inlet shuttle contacting the inlet valve poppet. Preferably, the outlet shuttle and/or inlet shuttle comprises magnetic material.

5

In a further aspect, the outlet shuttle comprises material which is magnetically inductive and the outlet valve trigger comprises an inductive element capable of inducing magnetism therein and/or the inlet shuttle comprises material which is magnetically inductive and the inlet valve trigger comprises an inductive element

10

capable of inducing magnetism therein.

Preferably, either or both of the outlet valve trigger or the inlet valve trigger is a pneumatic trigger.

15

Preferably, either or both of the outlet valve trigger or the inlet valve trigger is a hydraulic trigger. More preferably, the hydraulic trigger comprises a fluid-filled bag or tube capable of transferring hydraulic force.

20

The invention will now be described further with reference to the accompanying drawing in which:

Figure 1 is a sectional view of a first metering valve in accord with the present invention;

25

Figure 2 is a sectional view of a second metering valve in accord with the present invention;

Figure 3 is a sectional view of a third metering valve in accord with the present invention;

30

Figure 4 is a sectional view of a fourth metering valve in accord with the present invention;

35

Figure 5a is a sectional view of a fifth metering valve in accord with the present invention;

Figure 5b is a sectional view of a detail of the valve of Figure 5a;

Figure 6 is a sectional view of a sixth metering valve in accord with the present invention;

Figure 7 is a plan view of the valve actuation mechanism of a seventh metering valve in accord with the present invention;

Figures 8a to 8d show various forms of poppet valve suitable for use in accord with the invention;

Figure 9 is a sectional view of a seventh metering valve in accord with the invention;

Figure 10 is a sectional view of an eighth metering valve in accord with the invention; and

Figure 11 is a sectional view of a ninth metering valve in accord with the invention.

Figure 1 shows an aerosol metering valve herein. The valve comprises a valve body 10 which defines a metering chamber 12 and a sampling chamber 14. The metering chamber 12 has an inlet 20 permitting flow of aerosol from the sampling chamber 14 which in turn receives aerosol from a container (not shown) and an outlet 30 permitting dispensing of aerosol from the metering chamber 12. The inlet 20 is provided with valve means comprising a valve seat 22 and a valve poppet in the form of a metal ball 24. The metal ball 24 is biased towards the valve seat 22 by the action of spring 26. The outlet 30 is also provided with valve means comprising a valve poppet in the form of a metal ball 34 held by a spring 36 in biased contact with a valve seat 32. The valve body 10 is within a housing 6 shaped such as to define a circular track 8 running upwardly in parallel with the exterior of the valve body 10. Within the track 8 is contained a magnetic ring 40 which is movable up and down the track 8.

Actuation of the valve of Figure 1 is achievable by movement of the magnetic ring 40 which can magnetically interact with the metal ball valves 24,34 to dislodge them from their seats 22, 32. Movement of magnetic ring itself is for example, achievable by use of a second magnet (not shown). In a typical operation the inlet 20 valve will first be opened to allow metered flow of aerosol from the sampling chamber 14 into the metering chamber 12. The outlet 30 valve is then opened to allow for dispensing of the aerosol.

Figure 2 shows an aerosol metering valve herein. The valve comprises a valve body 110 which defines a metering chamber 112 and a sampling chamber 114. The metering chamber has an inlet 120 permitting flow of aerosol from the sampling chamber 114 and an outlet 130 permitting dispensing of aerosol from the metering chamber 112. The inlet 120 is provided with valve means comprising a valve seat 122 and a valve poppet in the form of a resilient ball 124. The ball 124 is biased towards the valve seat 122 by the action of spring 126. The outlet 130 is also provided with valve means comprising a valve poppet in the form of a ball 134 biased into contact with a valve seat 132 by action of spring 136. The valve body 110 is within housing 106 and the housing is provided with fixing screws 107, 109 for fixing the valve to an aerosol container (not shown). Movable magnetic rings 140, 142 contact the resilient balls 124, 134 of the inlet 120 and outlet 130 valves respectively. The magnetic rings 140, 142 are in turn in magnetic communication with shuttle magnets 150 and 152.

Actuation of the metering valve of Figure 2 is achievable by movement of the magnetic rings 140, 142 to physically dislodge the resilient balls 124, 134 from their respective seats 122, 132. Movement of magnetic rings is achievable by movement of the shuttle magnets 150, 152. The shuttle magnets 150, 152 may, in turn be coupled to a mechanical trigger such as a lever mechanism (not shown). In a typical operation the inlet 120 valve will first be opened to allow metered flow of aerosol from the sampling chamber 114 into the metering chamber 112. The outlet 130 valve is then opened to allow for dispensing of the aerosol.

Figure 3 shows an aerosol metering valve herein. The valve comprises a valve body 210 which defines a metering chamber 212. The metering chamber has an



inlet 220 permitting flow of aerosol from a container (not shown) and an outlet 230 permitting dispensing of aerosol from the metering chamber 212. The inlet 220 is provided with valve means comprising a valve seat 222 and a valve poppet in the form of a resilient plastic ball 224. The ball 224 is biased towards the valve seat 222 by the action of spring 226. The outlet 230 is also provided with valve means comprising a valve poppet in the form of a resilient plastic ball 234 biased into contact with a valve seat 232 by action of spring 236. The valve body 210 is within a housing 206. The housing 206 shaped is such as to define two circular cavities 208, 209, each running upwardly in parallel with a portion of the exterior of the valve body 210 and respectively positioned around the inlet 220 and outlet 230 valves. First and second circular solenoid cores 240, 242 are movably located within the first and second circular cavities 208, 209 and respectively engage the inlet and outlet ball valves 224, 234. The circular solenoid cores 240, 242 are in turn, positioned for inductive communication with outer solenoid coil windings magnets 250 and 252. The solenoid coil windings 250, 252 are connected to an electrical power source.

Actuation of the metering valve of Figure 3 is achievable by movement of the circular solenoid cores 240, 242 to physically dislodge the resilient balls 224, 234 in an upward direction from their respective seats 222, 232. Movement of the circular solenoid cores 240, 242 is in turn achievable by the application of electrical current to the solenoid coil windings 250, 252. In a typical operation the inlet 220 valve will first be opened to allow metered flow of aerosol into the metering chamber 212. The outlet 230 valve is then opened to allow for dispensing of the aerosol.

Figure 4 shows an aerosol metering valve herein. The valve comprises a valve body 310 which defines a metering chamber 312 and a sampling chamber 314. The metering chamber has an inlet 320 permitting flow of aerosol from the sampling chamber 314 and an outlet 330 permitting dispensing of aerosol from the metering chamber 312. The inlet 320 is provided with valve means comprising a valve seat 322 and a valve poppet in the form of a resilient ball 324. The ball 324 is biased towards the valve seat 322 by the action of spring 326. The outlet 330 is also provided with valve means comprising a valve poppet in the form of a resilient ball 334 biased into contact with a valve seat 332 by

action of spring 336. Gripping arms 340, 342 grip the resilient balls 324, 334 of the inlet 320 and outlet 330 valves respectively. The gripping arms are formed from a bimetallic strip wherein each of the bimetallic components thereof has a different coefficient of thermal expansion. The gripping arms 340, 342 are connectable to an electrical power source.

Actuation of the metering valve of Figure 4 is achievable by movement of the gripping arms 340, 342 to physically dislodge the resilient balls 324, 334 from their respective seats 322, 332. Movement of the gripping arms 340, 342 is in turn achievable by the application of electrical current which causes deformation of the bimetallic strip from which the arms are formed. In a typical operation the inlet 320 valve will first be opened to allow metered flow of aerosol into the metering chamber 312. The outlet 330 valve is then opened to allow for dispensing of the aerosol.

Figure 5a shows an aerosol metering valve herein and Figure 5b shows a detail of this valve when the inlet valve is in the open position. The metering valve comprises a valve body 410 which defines a metering chamber 412 and a sampling chamber 414. The metering chamber has an inlet 420 permitting flow of aerosol from the sampling chamber 414 and an outlet 430 permitting dispensing of aerosol from the metering chamber 412. The inlet 420 is provided with valve means comprising a valve seat 422 and a valve poppet in the form of a resilient ball 424. The ball 424 is biased towards the valve seat 422 by the action of spring 426. The outlet 430 is also provided with valve means comprising a valve poppet in the form of a resilient ball 434 biased into contact with a valve seat 432 by action of spring 436. Shaped, flexible elastomer bags 440, 442 sit within and on both sides of access holes 416, 418 provided in the sampling chamber 414 and metering chamber 412 respectively. The elastomer bags 440, 442 contain fluid material. It may be seen that one portion of each of the elastomer bags 440, 442 contacts the resilient balls 424, 434 of the inlet 420 and outlet 430 valves respectively. It may also be seen that another portion of each of the elastomer bags 440, 442 contacts an impacting arm 450 which is pivoted at pivot 454. The impacting arm 450 is itself connected to handle 456 which may itself be attached to a breath-actuable vane (not shown).

Actuation of the metering valve of Figures 5a and 5b is achievable by impacting the flexible, fluid-filled elastomer bags 440, 442 to physically dislodge the resilient balls 424, 434 from their respective seats 422, 432. Impaction of the elastomer bags 440, 442 is in turn achievable by the impacting movement of the impacting arm 450. The bags 440, 442 are shaped such as to deform upon impact to allow for transfer of the energy of impaction through the fluid contents. The deformation of one of the bags 440 on being struck by the impacting arm 450 is shown in Figure 5b which also shows the dislodgement of the resilient ball 424 from its seat 422. In a typical operation the inlet 420 valve will first be opened to allow metered flow of aerosol into the metering chamber 412. The outlet 430 valve is then opened to allow for dispensing of the aerosol. It will be appreciated that the illustrated pivotal mounting 454 of the impacting arm 450 only allows for impaction of one of the elastomer bags 440, 442, and hence opening of only one of the inlet 420 or outlet 430 valves, at a time.

Figure 6 shows an aerosol metering valve herein. The valve comprises a valve body 510 which defines a metering chamber 512 and a sampling chamber 514. The metering chamber has an inlet 520 permitting flow of aerosol from the sampling chamber 514 and an outlet 530 permitting dispensing of aerosol from the metering chamber 512. The inlet 520 is provided with valve means comprising a valve seat 522 and a valve poppet in the form of a resilient ball 524. The ball 524 is biased towards the valve seat 522 by the action of spring 526. The outlet 530 is also provided with valve means comprising a valve poppet in the form of a ball 534 biased into contact with a valve seat 532 by action of spring 536. The valve body 510 is within a housing 506 and the housing is provided with fixing screws 505, 507 for fixing the valve to an aerosol container 503 (shown in part only). Shaped pins 540, 542 sit within and on both sides of access holes 516, 518 provided in the sampling chamber 514 and metering chamber 512 respectively. It may be seen that the tail end of each of the shaped pins 540, 542 contacts the resilient balls 524, 534 of the inlet 520 and outlet 530 valves respectively. It may also be seen that the head of each of the pins 540, 542 contacts an elastomer diaphragm 546, 548 which in turn contacts double-headed transfer pins 546, 548. The elastomer diaphragms 546, 548 and the transfer pins 550, 552 are mounted in side compartments of the valve body. The outer heads of the transfer pins 546, 548 are impactable by

an impacting arm 560 which is pivoted at pivot 564. The impacting arm 560 is may itself connected to a breath-actuable vane (not shown).

5 Actuation of the metering valve of Figure 6 is achievable by movement of the shaped pins 540, 542 to physically dislodge the resilient balls 524, 534 from their respective seats 522, 532. Movement of the shaped pins 540, 542 is in turn achievable by impacting the elastomer diaphragms 546, 548 with their respective transfer pins 550, 552 following an impact by the impacting arm 560. In a typical operation the inlet 520 valve will first be opened to allow metered  
10 flow of aerosol into the metering chamber 512. The outlet 530 valve is then opened to allow for dispensing of the aerosol. It will be appreciated that the illustrated pivotal mounting 564 of the impacting arm 560 only allows for impaction of one of the transfer pins 550, 552, and hence opening of only one of the inlet 520 or outlet 530 valves, at a time.

15 Figure 7 shows a simplified, schematic representation of a poppet valve actuation mechanism suitable for use in an aerosol metering valve herein. The metering valve might, for example be of a type similar to those shown in Figures 1 to 6 but including the poppet valve actuation mechanism now described. The portion of the valve body 610 which defines a metering chamber 612 is shown.  
20 The metering chamber has an outlet 630 permitting dispensing of aerosol from the metering chamber 612. The outlet 630 is provided with valve means comprising a valve poppet in the form of a resilient ball 634 biased into contact with a valve seat 632 by action of spring 636. An actuator rod 642 sits within and on both sides of an access hole 618 provided in the metering chamber 612. The  
25 tail end of the actuator rod 642 contacts the resilient ball 634 of the outlet 630 valve. The shaft of the actuator rod is housed within torque tube 652 and a handle 656 is provided to the head of the actuator rod.

30 Actuation of the valve of Figure 7 is achievable by rotating the actuator rod 642 such that its tail end physically dislodges the resilient ball 634 from its seat 622. The actuator rod 642 is rotated by use of the handle 656 at its head.

35 Figures 8a to 8d show various forms of poppet valve suitable for use in accord with the invention. These employ valve poppets having different forms. These

alternative valve poppets may be used in the metering valves of Figures 1 to 6 or the poppet valve actuation mechanism of Figure 7 instead of the ball valve poppets shown therein.

5 In more detail, Figures 8a to 8d show a valve body 710a-d supporting a valve seat 732a-d and a valve poppet 734a-d which sits on valve seat 732a-d. In Figure 8a the valve poppet 734a is in the form of a mushroom. In Figure 8b the valve poppet 734b is in the form of a cone. In Figure 8c the valve poppet 734c is in the form of a disc. In Figure 8d the valve poppet 734d is in the form of a plug.

10

Figure 9 shows an aerosol metering valve herein in the rest position. The valve comprises a valve body 810 which defines a metering chamber 812 and a sampling chamber 814. The metering chamber has an inlet 820 permitting flow of aerosol from the sampling chamber 814 and an outlet 830 permitting dispensing of aerosol from the metering chamber 812. The inlet 820 is provided with valve means comprising a valve seat 822 and a valve poppet in the form of a first shaped magnet 824 which has a flexible seal 823 provided thereto. The seal 823 is biased away from the valve seat 822 by the repulsive action of toroidal magnet 850. The outlet 830 is also provided with valve means comprising a valve poppet in the form of a second shaped magnet 834 having a flexible seal 833 biased into contact with a valve seat 832 by the attractive action of toroidal magnet 850. Both shaped magnets 824, 834 are chamfered to provide flow passageways therethrough.

15

20

25 Actuation of the metering valve of Figure 9 is achievable by movement of the toroidal magnet 850 downwards which removes the repulsive force from the first shaped magnet 824 which may therefore contact the valve seat 822 closing the inlet 820. Simultaneously, the toroidal magnet 850 attracts the second shaped magnet 834 which moves off its seat 834 thereby opening the outlet 830. The toroidal magnet 850 may in turn be coupled to a mechanical trigger such as a lever mechanism (not shown).

30

35

Figure 10 shows an aerosol metering valve herein. The metering valve comprises a valve body 910 which defines a metering chamber 912 and a sampling chamber 914. The sampling chamber 914 is funnel-shaped to

encourage ready flow of aerosol from the container to the metering chamber 912. The metering chamber 912 has an inlet 920 permitting flow of aerosol from the sampling chamber 914 and an outlet 930 permitting dispensing of aerosol from the metering chamber 912. The inlet 920 is provided with valve means comprising a valve seat 922 and a valve poppet in the form of a resilient ball 924. The ball 924 is biased towards the valve seat 922 by the action of spring 926. The outlet 930 is also provided with valve means comprising a valve poppet in the form of a resilient ball 934 biased into contact with a valve seat 932 by action of spring 936. The valve body 910 is provided with fixing screws 905, 907 for fixing the valve to an aerosol container 903 (shown in part only). Shaped pins 940, 942 sit within and on both sides of access holes 916, 918 provided in the sampling chamber 914 and metering chamber 912 respectively. It may be seen that the tail end of each of the shaped pins 940, 942 contacts the resilient balls 924, 934 of the inlet 920 and outlet 930 valves respectively. It may also be seen that each of the pins 940, 942 is biased to a rest position by spring 944, 946 away from the respective resilient ball 924, 934. The outer heads of the transfer pins 941, 943 are shaped for impact. A suitable impactor (not shown) might for example, comprise an impacting arm as shown in Figure 6 which may itself be connected to a breath-actuable vane.

Actuation of the metering valve of Figure 10 is achievable by impacting the heads 941, 943 of the shaped pins 940, 942 to physically dislodge the resilient balls 924, 934 from their respective seats 922, 932. The action of the springs 944, 946 will return each pin to the rest position on removal of the impacting force. In a typical operation the inlet 920 valve will first be opened to allow metered flow of aerosol into the metering chamber 912. The outlet 930 valve is then opened to allow for dispensing of the aerosol. The impactor may be configured to allow for impaction of one of the shaped pins 940, 942, and hence opening of only one of the inlet 920 or outlet 930 valves, at a time.

Figure 11 shows an aerosol metering valve herein. The metering valve comprises a valve body 1010 which defines a metering chamber 1012 and a sampling chamber 1014. The metering chamber 1012 has an inlet 1020 permitting flow of aerosol from the sampling chamber 1014 and an outlet 1030 permitting dispensing of aerosol from the metering chamber 1012. The inlet

1020 is provided with valve means comprising a valve seat 1022 and a valve poppet in the form of a cone 1024. The cone 1024 is biased towards the valve seat 1022 by the action of spring 1026 (rest position). The outlet 1030 is also provided with valve means comprising a valve poppet in the form of a cone 1034  
5 biased into contact with a valve seat 1032 by action of spring 1036 (rest position). Shaped actuator pins 1040, 1042 sit within and on both sides of access passages 1016, 1018 provided in the valve body 1010. It may be seen that the tail end of each of the actuator pins 1040, 1042 connects with the cone poppets 1024, 1034 of the inlet 1020 and outlet 1030 valves respectively. It may  
10 also be seen that the tail end each of the pins 1040, 1042 is provided with protective bellow seals 1046, 1048 which provide a seal between the cone poppets 1024, 1034 and the actuator pins 1040, 1042. The outer heads of the transfer pins 1041, 1043 are shaped for impact. A suitable impactor (not shown) might for example, comprise an impacting arm as shown in Figure 6 which may  
15 itself be connected to a breath-actuable vane.

Actuation of the metering valve of Figure 11 is achievable by impacting the heads 1041, 1043 of the actuator pins 1040, 1042 to physically dislodge the cone poppets 1024, 1034 from their respective seats 1022, 1032. The action of  
20 the springs 1026, 1036 will return each pin 1040, 1042 to the rest position on removal of the impacting force. In a typical operation the inlet 1020 valve will first be opened to allow metered flow of aerosol into the metering chamber 1012. The outlet 1030 valve is then opened to allow for dispensing of the aerosol. The impactor may be configured to allow for impaction of one of the actuator pins  
25 1040, 1042, and hence opening of only one of the inlet 1020 or outlet 1030 valves, at a time.

The aerosol container and valve of the invention is suitable for dispensing medicament, particularly for the treatment of respiratory disorders such as  
30 asthma and chronic obstructive pulmonary disease (COPD).

Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or  
35 nedocromil; antiinfectives e.g., cephalosporins, penicillins, streptomycin,

5 sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti- inflammatories, e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone acetonide; antitussives, e.g., noscapine; bronchodilators, e.g.,  
10 albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro- $\alpha$ -[[[6-[2-(2-pyridinyl)ethoxy] hexyl]methyl] benzenemethanol; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones,  
15 e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g.,  
lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

20 Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

25 Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate).

30 It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

35 The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use



claims and may include, by way of example and without limitation, one or more of the following claims:

Claims

1. Metering valve for an aerosol container comprising

a valve body defining a metering chamber;

said metering chamber having an inlet and an outlet, said inlet permitting flow of aerosol from said container to the metering chamber and said outlet permitting dispensing of aerosol from the metering chamber;

the inlet having an inlet valve reversibly actuatable from an open to a closed position; and

the outlet having an outlet valve reversibly actuatable from a dispensing to a non-dispensing position, wherein said outlet valve comprises an outlet valve seat and an outlet valve poppet in biasable contact therewith.

2. Metering valve according to claim 1, wherein said inlet valve comprises an inlet valve seat and an inlet valve poppet in biasable contact therewith.

3. Metering valve according to either of claims 1 or 2, additionally comprising an outlet valve mover for moving the outlet valve poppet out of contact with the outlet valve seat.

4. Metering valve according to either of claims 2 or 3, additionally comprising an inlet valve mover for moving the inlet valve poppet out of contact with the inlet valve seat.

5. Metering valve according to either of claims 3 or 4, wherein either or both of said inlet valve mover or said outlet valve mover is mechanically actuatable.

6. Metering valve according to either of claims 3 or 4, wherein either or both of the inlet valve mover or the outlet valve mover is electrically actuable.

5 7. Metering valve according to claim 6, wherein either or both of the inlet valve mover or the outlet valve mover comprises a multi-component strip or wire which is deformable in response to electrical current flow.

10 8. Metering valve according to claim 7, wherein said multi-component strip or wire comprises multiple layers of different metals.

9. Metering valve according to claim 8, wherein the multi-component strip comprises a bimetallic strip.

15 10. Metering valve according to either of claims 7 or 8, wherein the multi component strip comprises at least one piezoelectric or piezoresistive material.

11. Metering valve according to claim 7, wherein said multi-component wire comprises a nickel-titanium alloy.

20 12. Metering valve according to either of claims 3 or 4, wherein either or both of the inlet valve mover or the outlet valve mover is magnetically actuable.

25 13. Metering valve according to claim 12, wherein either or both of the inlet valve mover or the outlet valve mover comprises magnetic material or material which is magnetically inductive.

14. Metering valve according to either of claims 3 or 4, wherein either or both of the inlet valve mover or the outlet valve mover is pneumatically actuable.

30 15. Metering valve according to either of claims 3 or 4, wherein either or both of the inlet valve mover or the outlet valve mover is hydraulically actuable.

35 16. Metering valve according to claim 14, wherein either or both of the inlet valve mover or the outlet valve mover comprises a fluid-filled bag or tube capable of transferring hydraulic force.

17. Metering valve according to any of claims 1 to 16, wherein the outlet valve poppet has a form selected from the group consisting of a ball, a mushroom, a cone, a disc and a plug.

5

18. Metering valve according to any of claims 2 to 17, wherein the inlet valve poppet has a form selected from the group consisting of a ball, a mushroom, a cone, a disc and a plug.

10 19. Metering valve according to any of claims 1 to 18, wherein said valve body additionally defines a sampling chamber and the inlet permits flow from the sampling chamber to the metering chamber.

15 20. Metering valve according to any of claims 1 to 19, wherein the metering chamber has a variable metering volume.

21. Aerosol container comprising a metering valve according to any of claims 1 to 20.

20 22. Aerosol container according to claim 21, wherein the valve body of the metering valve is not movable relative to the container.

23. Aerosol container according to either of claims 21 or 22 comprising a suspension of a medicament in a propellant.

25

24. Aerosol container according to claim 23, wherein, said propellant comprises liquefied HFA134a, HFA-227 or carbon dioxide.

30 25. Aerosol container according to either of claims 23 or 24, wherein the medicament is selected from the group consisting of albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate, salts or solvates thereof and any mixtures thereof.

35 26. Aerosol container according to either of claims 22 or 23 comprising a compressed gas, preferably compressed air.

27. Inhalation device for dispensing medicament to a patient comprising  
a housing;

5

an aerosol container, locatable within said housing, said aerosol container  
comprising a metering valve according to any of claims 1 to 20; and

10

an outlet valve trigger for triggering the movement of the outlet valve poppet out  
of contact with the outlet valve seat.

15

28. Inhalation device according to claim 27, wherein the aerosol container  
comprises a metering valve according to any of claims 2 to 20, additionally  
comprising an inlet valve trigger for triggering the movement of the inlet valve  
poppet out of contact with the inlet valve seat.

20

29. Inhalation device according to either of claims 27 or 28, wherein either  
or both of said outlet valve trigger or said inlet valve trigger is triggerable in  
response to the breath of a patient.

25

30. Inhalation device according to claim 29, wherein either or both of the  
outlet valve trigger or the inlet valve trigger communicates with a sensor which  
senses the breath of a patient.

30

31. Inhalation device according to claim 30, wherein said sensor comprises  
an breath-movable element which is movable in response to the breath of a  
patient.

35

32. Inhalation device according to claim 31, wherein said breath-movable  
element is selected from the group consisting of a vane, a sail, a piston and an  
impeller.

33. Inhalation device according to claim 30, wherein said sensor comprises  
a pressure sensor for sensing the pressure profile associated with the breath of  
a patient.

34. Inhalation device according to claim 30, wherein said sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a patient.

5

35. Inhalation device according to claim 30, wherein said sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a patient.

10

36. Inhalation device according to claim 30, wherein said sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a patient.

15

37. Inhalation device according to claim 30, wherein said sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a patient.

20

38. Inhalation device according to claim 30, wherein said sensor comprises a piezoelectric or piezoresistive element.

39. Inhalation device according to any of claims 27 to 38, wherein the outlet valve trigger and the inlet valve trigger are independently triggerable.

25

40. Inhalation device according to any of claims 27 to 38, wherein the outlet valve trigger and the inlet valve trigger are triggerable in a coupled fashion.

30

41. Inhalation device according to any of claims 27 to 40, wherein either or both of the outlet valve trigger or the inlet valve trigger is a mechanical trigger.

42. Inhalation device according to claim 41, wherein said mechanical trigger comprises a lever mechanism.

35

43. Inhalation device according to claim 41, wherein said mechanical trigger comprises a torque transfer mechanism.

44. Inhalation device according to any of claims 27 to 40, wherein either or both of the outlet valve trigger or the inlet valve trigger comprises a multi-component strip which is deformable in response to electrical current flow.

5

45. Inhalation device according to claim 44, wherein said multi-component strip comprises multiple layers of different metals.

10

46. Inhalation device according to claim 45, wherein said multi-component strip comprises a bimetallic strip.

15

47. Inhalation device according to either of claims 44 or 45, wherein said multi-component strip comprises at least one piezoelectric or piezoresistive material.

20

48. Inhalation device according to any of claims 27 to 40, wherein either or both of the outlet valve trigger or the inlet valve trigger is a magnetic trigger.

49. Inhalation device according to claim 48, wherein the outlet valve trigger interacts magnetically with the outlet valve poppet and/or the inlet valve trigger interacts magnetically with the inlet valve poppet.

25

50. Inhalation device according to claim 48, wherein the outlet valve trigger interacts magnetically with a outlet shuttle contacting the outlet valve poppet and/ or the inlet valve trigger interacts magnetically with a inlet shuttle contacting the inlet valve poppet.

30

51. Inhalation device according to claim 50, wherein the outlet shuttle and/or inlet shuttle comprises magnetic material.

52. Inhalation device according to either of claims 50 or 51, wherein the outlet shuttle comprises material which is magnetically inductive and the outlet valve trigger comprises an inductive element capable of inducing magnetism therein and/or the inlet shuttle comprises material which is magnetically

inductive and the inlet valve trigger comprises an inductive element capable of inducing magnetism therein.

53. Inhalation device according to any of claims 27 to 40, wherein either or  
5 both of the outlet valve trigger or the inlet valve trigger is a pneumatic trigger.

54. Inhalation device according to any of claims 27 to 40, wherein either or  
both of the outlet valve trigger or the inlet valve trigger is a hydraulic trigger.

10 55. Inhalation device according to claim 54, wherein the hydraulic trigger  
comprises a fluid-filled bag or tube capable of transferring hydraulic force.

15

20



Abstract

5 There is provided a metering valve for an aerosol container comprising a valve  
body defining a metering chamber; the metering chamber having an inlet and an  
outlet, the inlet permitting flow of aerosol from said container to the metering  
chamber and the outlet permitting dispensing of aerosol from the metering  
chamber; the inlet having an inlet valve reversibly actuatable from an open to a  
closed position; and the outlet having an outlet valve reversibly actuatable from a  
dispensing to a non-dispensing position, wherein the outlet valve comprises a  
10 outlet valve seat and an outlet valve poppet in biasable contact therewith.

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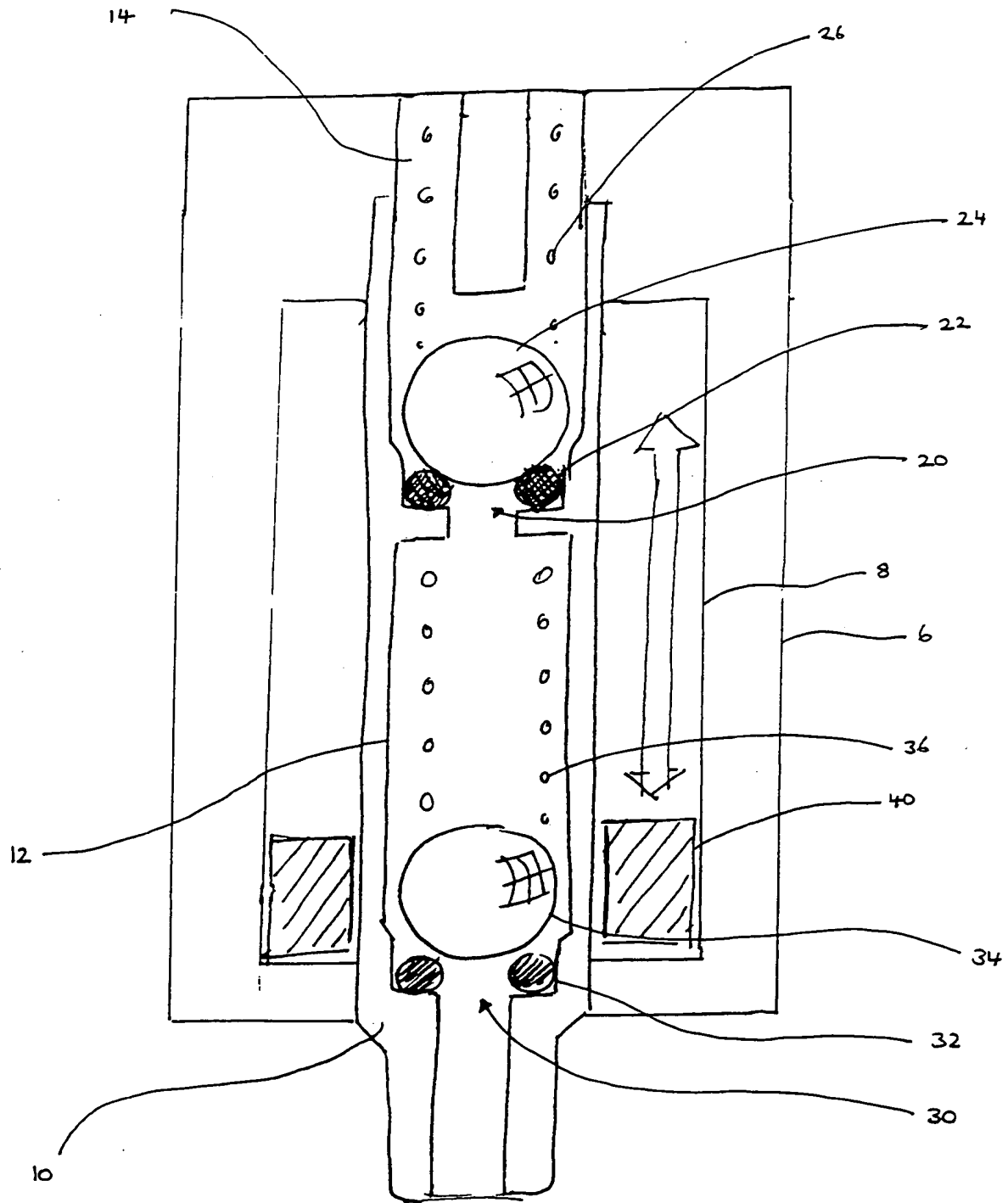


Fig. 1

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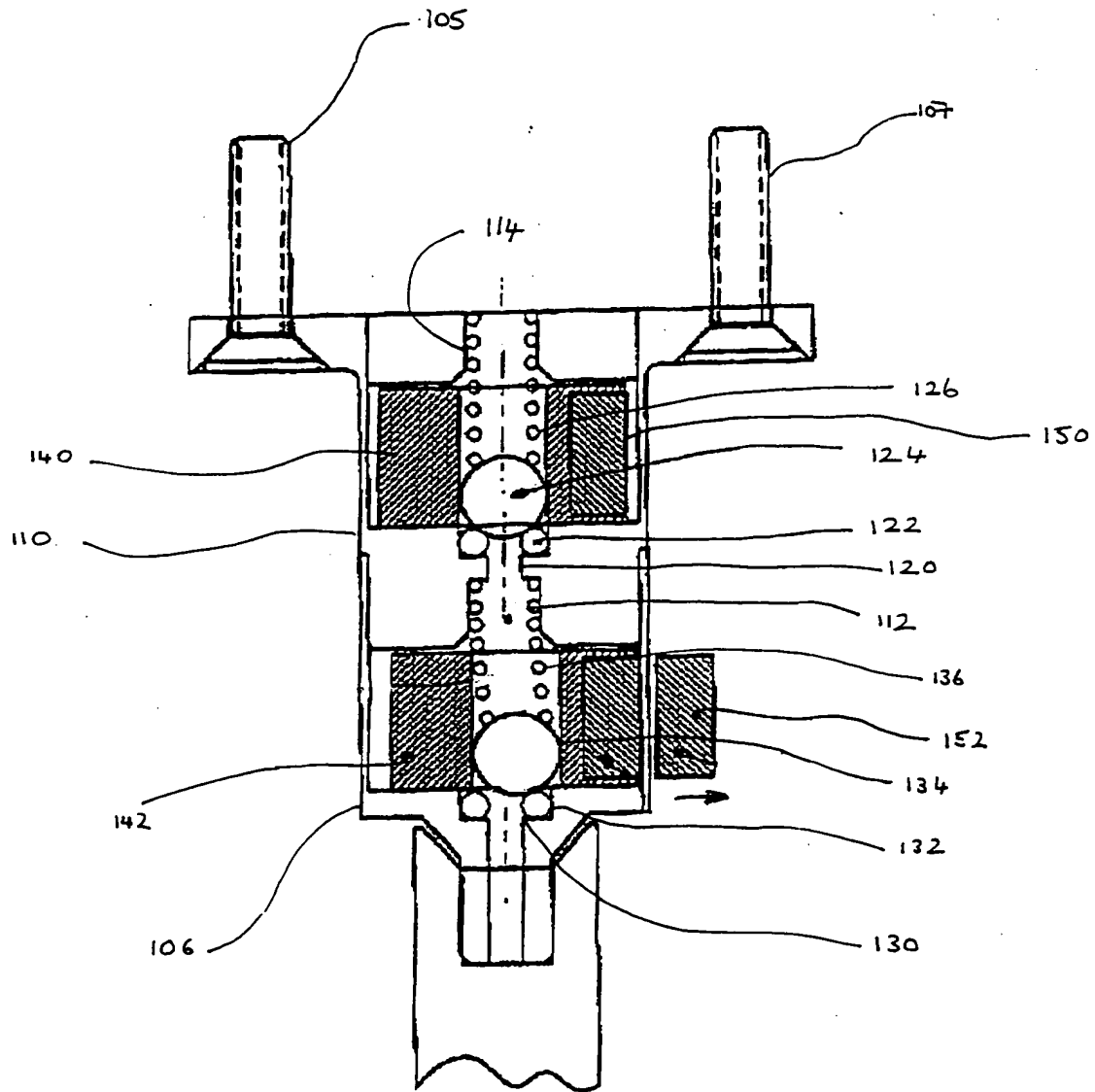


Fig. 2

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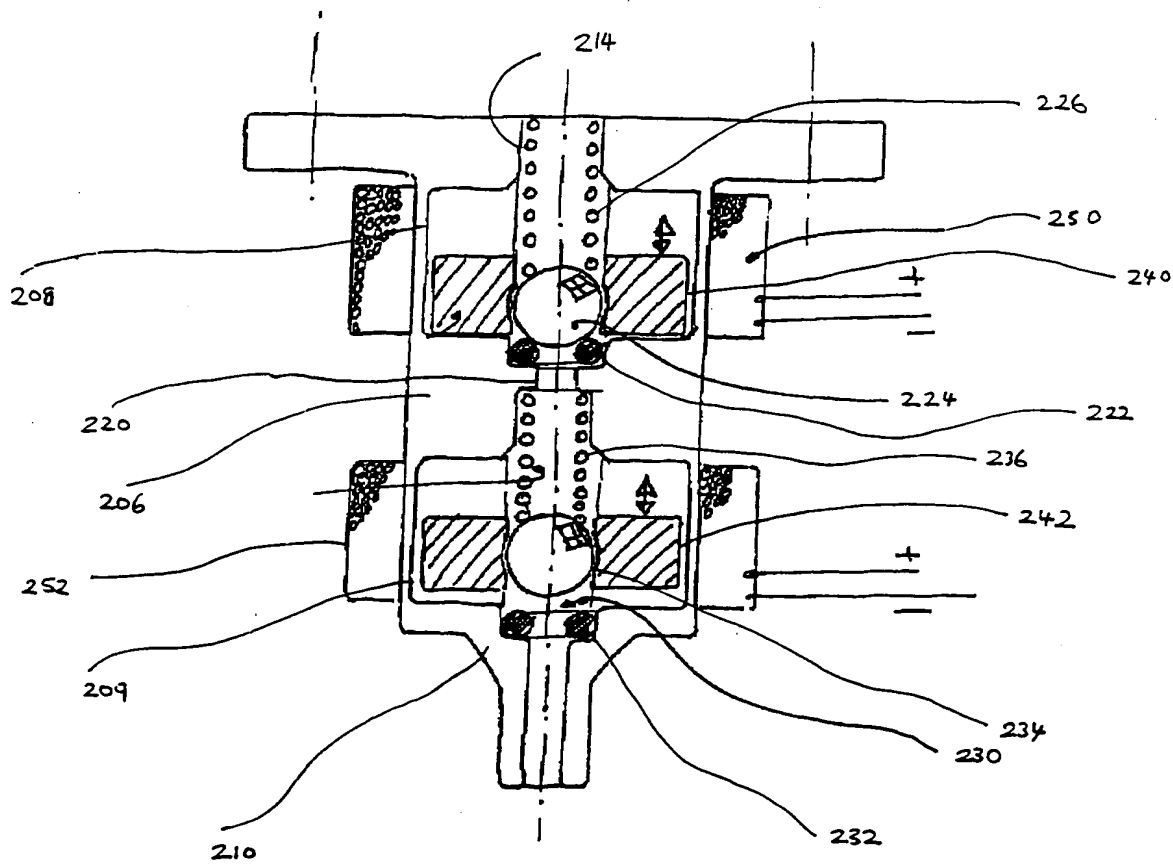


Fig. 3

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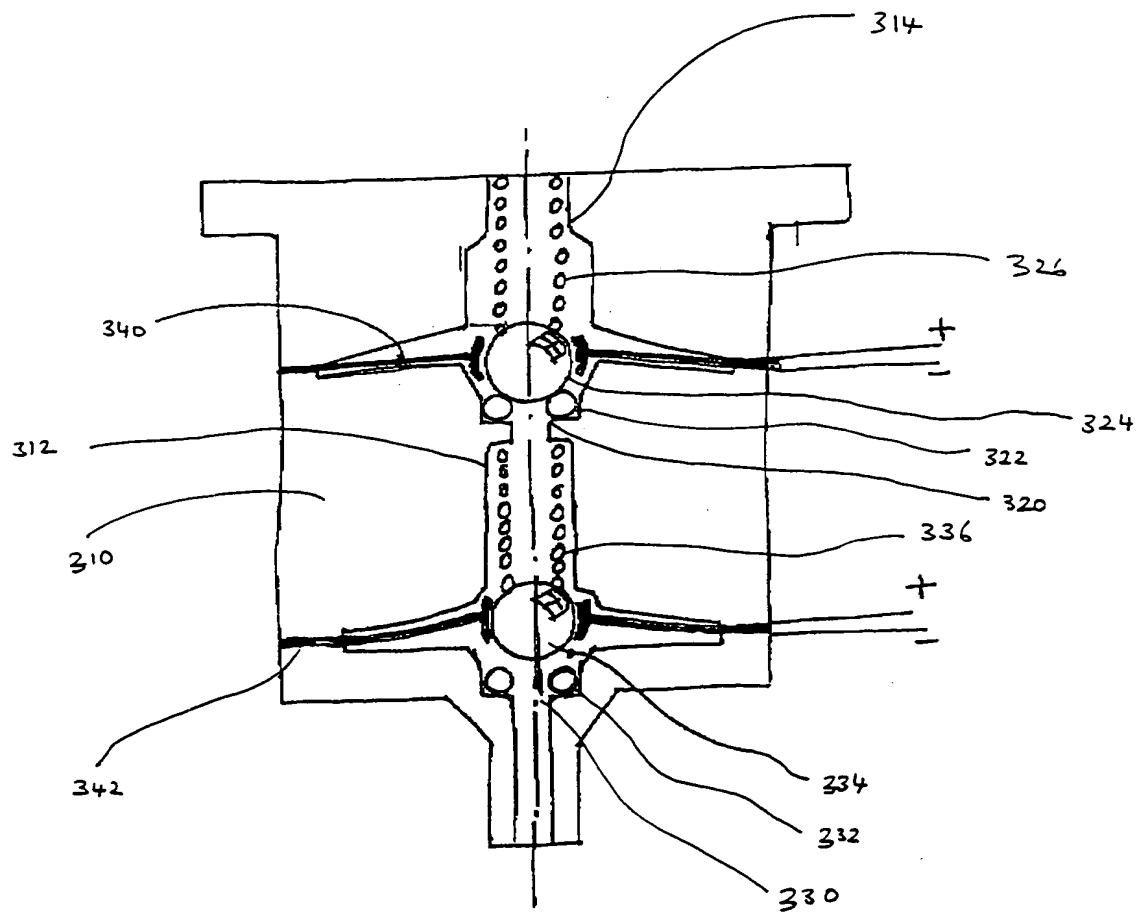


Fig. 4

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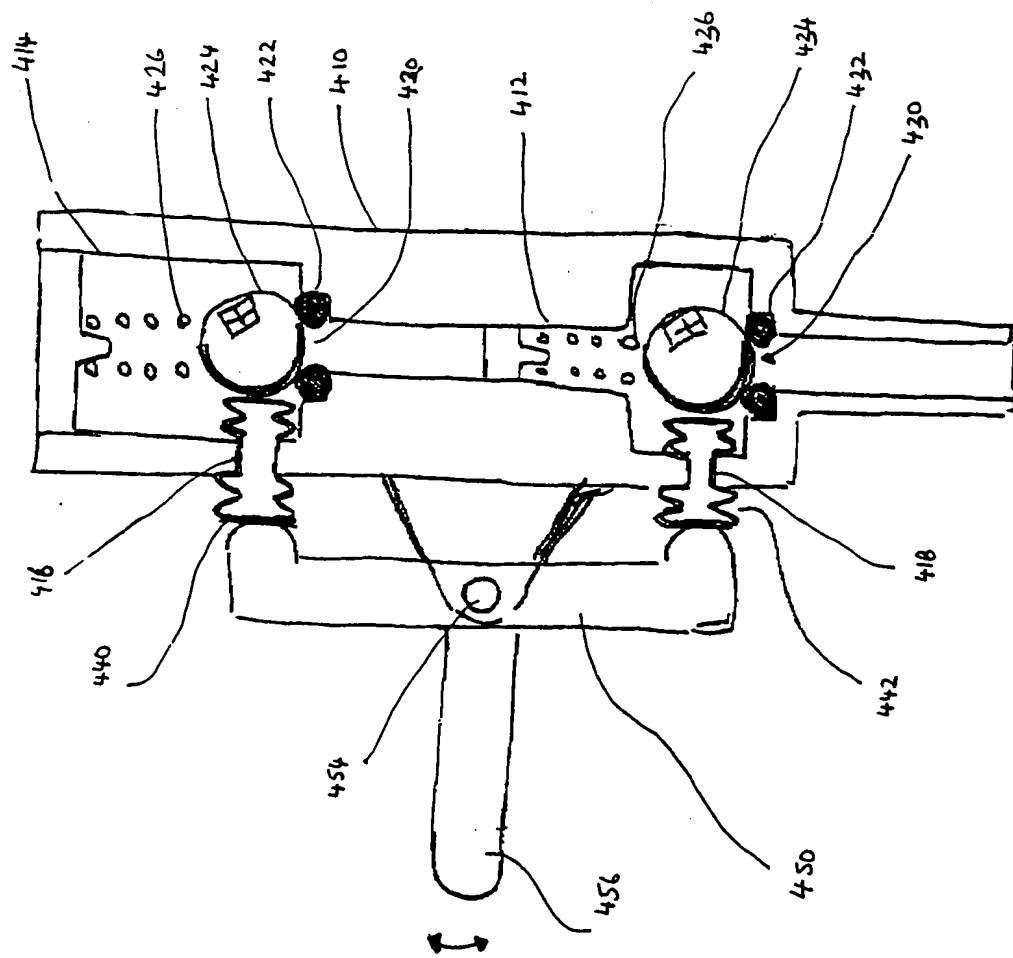


Fig. 5a

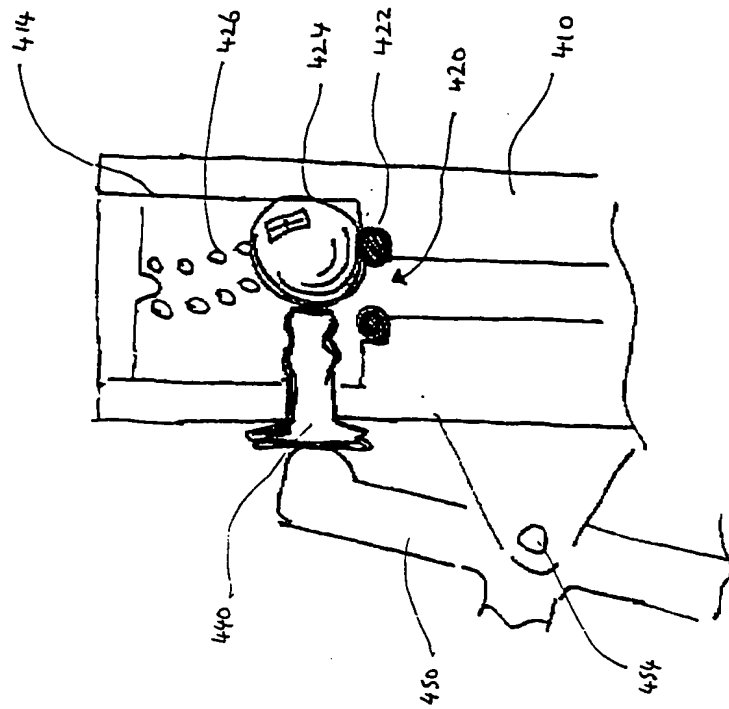


Fig. 5b

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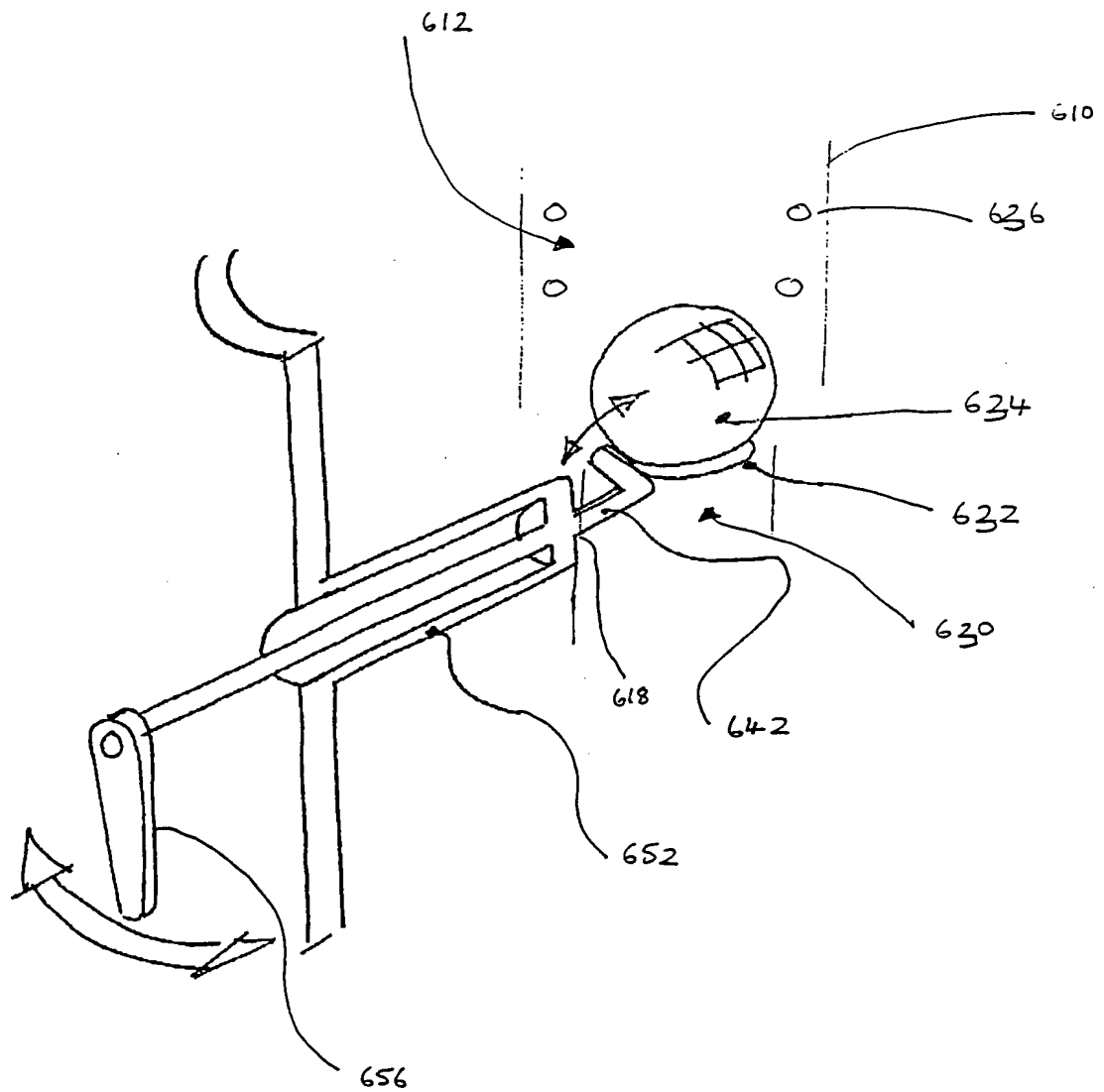


Fig. 7

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Fig. 8a

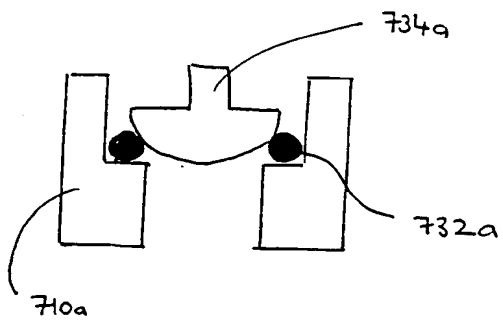


Fig. 8b

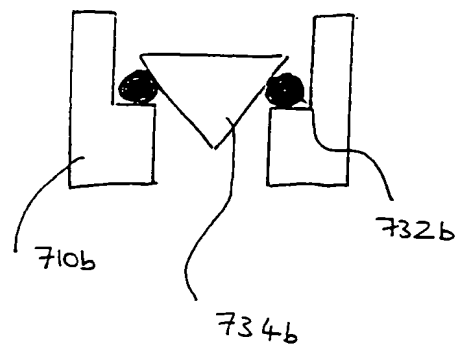


Fig. 8c

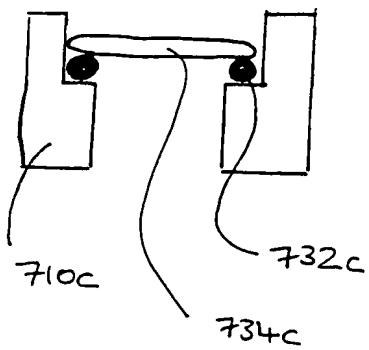
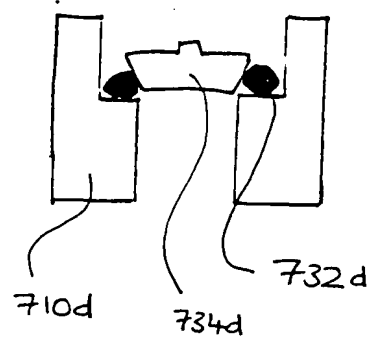


Fig. 8d



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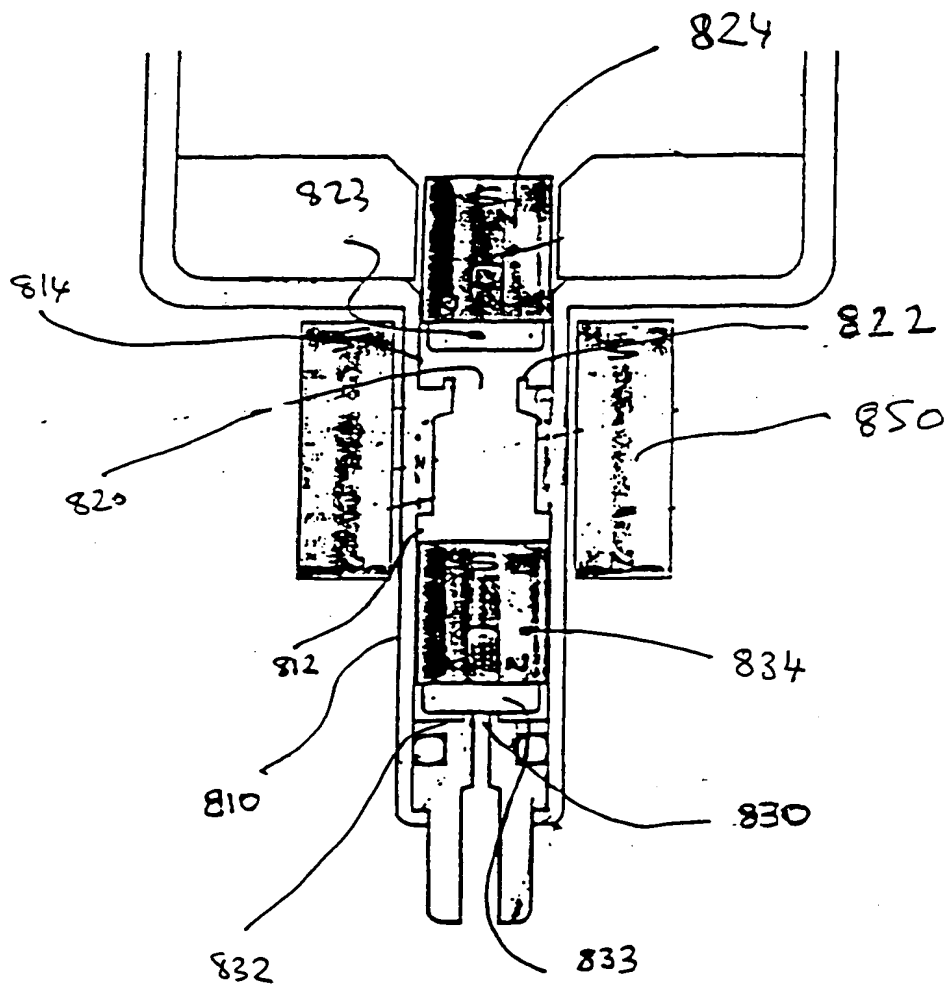


Fig. 9

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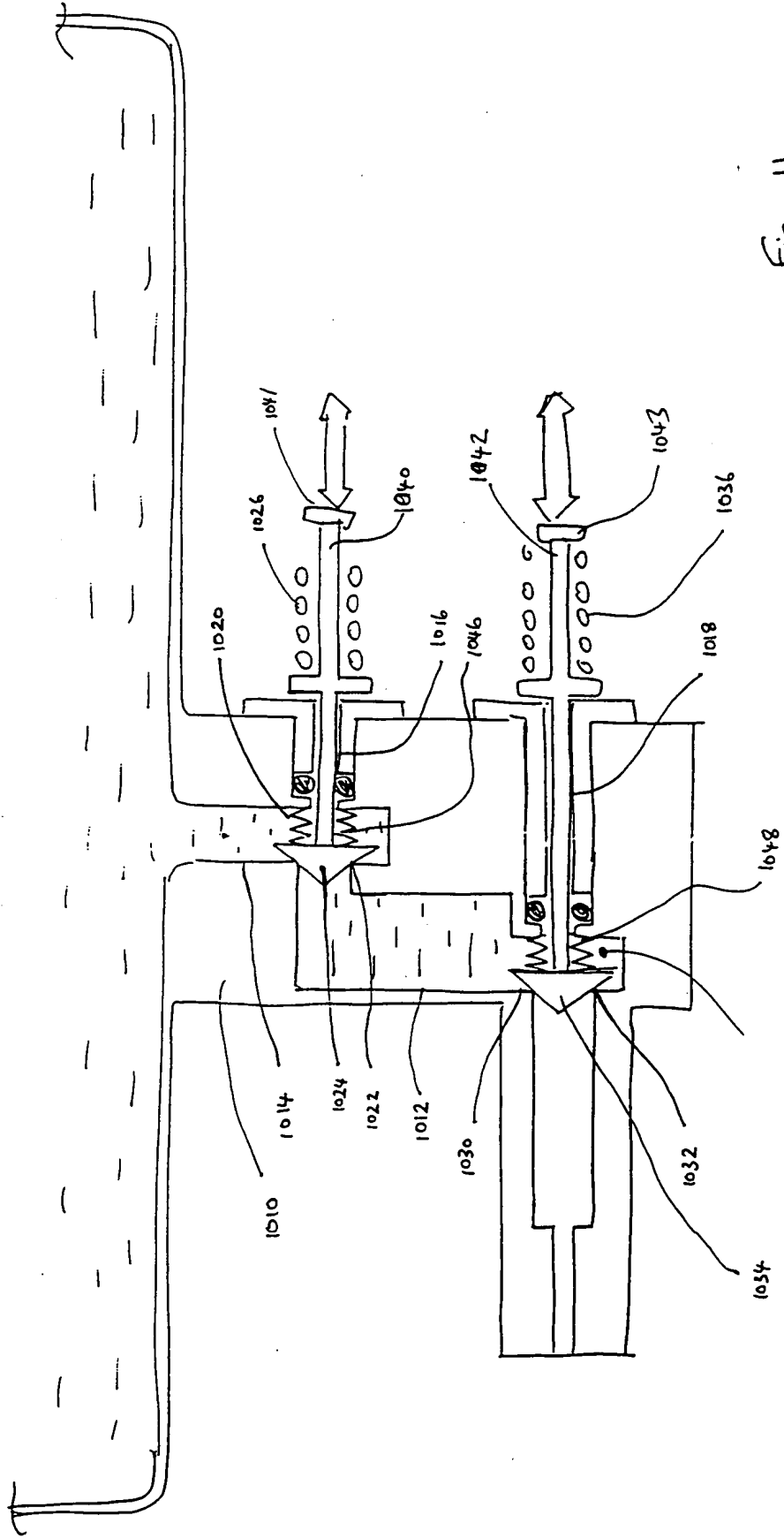


Fig. 11

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